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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/297,040	07/21/99	MOSE LARSEN	P 0785.0390004

HM12/0612

STERNE KESSLER GOLDSTEIN & FOX
1100 NEW YORK AVENUE NW
SUITE 600
WASHINGTON DC 20005-3934

EXAMINER	
ROBINSON,H	
ART UNIT	**PAPER NUMBER**
1653	10

DATE MAILED: 06/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/297,040	Larsen et al.
Examiner	**Art Unit**
Hope Robinson	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 8, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-27* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Election/Restriction

1. This is a Supplemental Restriction Requirement as claims 12 and 13 were missed in the previous communication mailed October 4, 2000 in Paper No. 6. Therefore, the previous Restriction Requirement has been vacated and the following has been instituted. It is noted that applicant elected with traverse Group II for examination on the merits in Paper No: 8.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6, drawn to an in vivo method for identifying a diabetes-mediating protein.
Group II, claim(s) 7-13, drawn to a diabetes mediating protein.
Group III, claim(s) 14, drawn to an in vitro method of identifying a protective or deleterious diabetes mediating protein.

If Group II is elected applicant needs to elect one protein from Table

1 or 2 for examination on the merits as the proteins are separate and/or distinct having different structure thus function and have been identified on page 1 of the specification as having differential expression.

Group IV, claim(s) 15-18, drawn to a transgenic non-human mammal.

Group V, claim(s) 19, 20, 24 and 25, drawn to a method of treating or preventing diabetes using an antisense sequence.

Group VI, claim(s) 19, 20, 24 and 25, drawn to a method of treating or preventing diabetes using an antibody.

Group VII, claim(s)19, 22-25, drawn to a method of treating or preventing diabetes using a protein.

Group VIII, claim(s) 19, 24, 25 and 26, drawn to a method of treating or preventing diabetes using polynucleotide.

Group IX, claim(s) 27, drawn to a method of identifying a compound capable of modulating the activity of a diabetes-mediating protein.

3. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories) A product and a process specially adapted for the manufacture of said product; or 2) A product and a process of use of said product, and a use of the said product; or the said product; or 4) A process and an apparatus or

1 or 2 for examination on the merits as the proteins are separate and/or distinct having different structure thus function and have been identified on page 1 of the specification as having differential expression.

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Group VI, claim(s) 19, 20, 24 and 25, drawn to a method of treating or preventing diabetes using an antibody.

Group VII, claim(s)19, 22-25, drawn to a method of treating or preventing diabetes using a protein.

Group VIII, claim(s) 19, 24, 25 and 26, drawn to a method of treating or preventing diabetes using polynucleotide.

Group IX, claim(s) 27, drawn to a method of identifying a compound capable of modulating the activity of a diabetes-mediating protein.

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An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories) A product and a process specially adapted for the manufacture of said product; or 2) A product and a process of use of said product, and a use of the said product; or the said product; or 4) A process and an apparatus or

means specifically designed for carrying out the said process; or 5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (MPEP 37 CFR 1.475).

The special technical feature of Group I is the identification of a diabetes mediating protein in vivo which requires the transplantation and removal of insulin secreting cells. The special technical feature of Group II is a diabetes mediating protein. The special technical feature of Group III is the identification of a protective or deleterious diabetes mediating protein in vitro wherein the cells are transfected with a nucleic acid sequence encoding a diabetes mediating protein. The special technical feature of Group IV is a transgenic non-human mammal and the method of using the same. The special technical feature of Group V is a method of treating or preventing diabetes or diabetes related disorders by administering an antisense sequence. The special technical feature of Group VI is a method of treating or preventing diabetes related disorders by administering an antibody. The special technical feature of Group VII is a method of treating or preventing diabetes or diabetes related disorders by administering a diabetes mediating protein. The special technical feature of Group V is a method of treating or preventing diabetes or diabetes related disorders by administering a polynucleotide.

Proteins, nucleic acid and antibody are structurally and functionally different compounds with different uses. Therefore, a method of treating or preventing diabetes or diabetes related disorders by administering these products are technically distinct. Furthermore, the method of identifying diabetes mediating protein is technically distinct from the transgenic non-human animal because these inventions have different modes of operation,

functions and effects. Thus, these inventions are technically distinct and have separate uses.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined though the requirement be traversed (37 CFR 1.17(I))

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor-ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Serial Number 09/297,040
Art Unit 1653

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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Hope A. Robinson, MS

Patent Examiner